

**K110823 PRISMAFLEX**Jun 17, 2011  
85 days to decisionK110823 · Product code: **KDI** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k110823/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Mar 24, 2011
Decision date	Jun 17, 2011
Days to decision	85 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Gambro Renal Products, Inc.</b>
Location	Lakewood, CO, US
Contact	KAE MILLER
510(k) history	13 submissions · 13 cleared · 2004-2014

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k110823/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 7, 2026